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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,492	03/21/2001	Mark A. Labow	4-31360A/USN	2101

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EXAMINER	
HOLLERAN, ANNE L	
ART UNIT	PAPER NUMBER
1642	11

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/813,492	LABOW ET AL.	
	Examiner	Art Unit	
	Anne Holleran	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) *3-5* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

1. The amendment filed 1/16/2003 is acknowledged. Claim 6 was added.

Claims 1-6 are pending.

Claims 3-5, drawn to non-elected inventions, are withdrawn from consideration.

Claims 1, 2 and 6 are examined on the merits.

Claim Rejections Withdrawn:

2. The rejection of claims 1 and 2 under 35 U.S.C. 102(e) as being rejected by Papsidero (U.S. 6,306,653; issued Oct. 23, 2001; filing date Sep. 3, 1998) is withdrawn in view of the amendment indicating that decreased hybridization signal is observed.

Claim Rejections Maintained:

3. The rejection of claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, for lack of enablement commensurate with the scope of the claims is maintained, and made against new claim 6. The amendment of claim 1 addressed the issue of the type of cancer to be detected, but failed to address the issue of the scope of the probes. Claim 1 is now drawn to methods for detection of breast cancer comprising providing a probe that comprises SEQ ID NO: 1 or comprises a fragment of SEQ ID NO: 1. The claim fails to recite specific hybridization conditions, and fails to recite that the claimed method are for the detection of mRNA encoding a protein encoded by SEQ ID NO: 1. Therefore, the scope of the claims is extremely broad and encompasses methods for the detection of breast cancer comprising providing probes that have

very little sequence similarity to the sequence of SEQ ID NO: 1. For example, in claim 2, dependent from claim 1, the probe may only have 10 nucleotides in common and may further include sequences not in common with SEQ ID NO: 1. Thus, the probes used in the claims may detect sequences that encode mRNA species or gene sequences that have very little in common with SEQ ID NO: 1, and for which there is no support in the specification as being associated with breast cancer.

New Grounds of Rejection:

4. Claims 1, 2 and 6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The basis for this amendment is that the amendment to claim 1 introduces new matter into the specification. The amendment adds the limitation "wherein suppressed hybridization compared to control levels indicates the presence of a breast tumor". The new matter that is introduced is the concept of a control, because the specification only describes one example of a control, which is not representative of the generic concept of a control as recited in the claims. The specification describes experiments where breast tumors are compared adjacent non-tumor breast tissue, and where loss of MEC mRNA expression compared to adjacent non-tumor tissue is observed in the breast tumor samples. This is the basis for making a method for the detection of a breast tumor. The specification does not describe any other controls. Therefore, applicant was not in possession of methods where any control may be used, but only to methods where

levels of MEC mRNA in a sample is compared to levels of MEC mRNA in adjacent non-cancerous breast tissue from the same individual.

5. Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being anticipated by either Band (U.S. Patent 6,153,387; issued 11/28/2000; effective filing date 6/6/1995) or Vogelstein et al (U.S. Patent 5,527,676; issued 6/18/1996; effective filing date 8/17/1992).

Claim 1 is drawn to methods of detection of breast cancer, comprising providing a probe that comprises a fragment of SEQ ID NO: 1, detecting hybridization where a decrease in hybridization signal indicates the presence of breast cancer. The scope of fragment may be as little a one nucleotide. Therefore, the probe may be a polynucleotide that comprises any 1 nucleotide of SEQ ID NO: 1, and the probe may be at least 10 nucleotides in length. The 10 nucleotide probe of claim 2 is not assumed to comprise 10 contiguous nucleotides from SEQ ID NO: 1, but to be at least 10 nucleotides in length and to comprise a fragment (as little as 1 nucleotide) of SEQ ID NO: 1.

Band discloses a methods for the detection of breast cancer in breast tissue, comprising contacting a biological sample that may be breast tissue with a probe that would comprise a fragment of SEQ ID NO:1, where a decrease in hybridization indicates that the patient has a malignancy (see claims 11 and 13) Band teaches a probe that is a NES1 cDNA fragment (col. 17, lines 42-45; and col. 10, lines 1-11) that is at least 10 nucleotides in length. Thus, Band discloses and claims the claimed methods.

Vogelstein discloses methods for the detection of breast cancer in breast tissue, comprising contacting a biological sample that may be breast tissue with a probe for the purpose

of detecting the loss of p53 nucleic acids, wherein a decrease in signal indicates the presence of breast cancer (see claims 1, 4, 5, and 19).

6. Claims 1, 2 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Band (supra) or Vogelstein (supra) in view of Coghlan (Coghlan, et al., Analytical Biochemistry, 149: 1-28, 1985).

Claims 1 and 6 are interpreted as drawn to methods of detection of breast cancer, comprising providing a probe that comprises a fragment of SEQ ID NO: 1, detecting hybridization where a decrease in hybridization signal indicates the presence of breast cancer, where the method of detection is in situ hybridization. Neither Band nor Vogelstein teaches methods comprising methods of in situ hybridization. However, hybridization histochemistry methods are well established in the art as evidenced by the teachings of Coghlan. Coghlan also teaches that in situ hybridzation is a research tool that provides the location of anatomical sites of gene expression (see abstract, and page 2, 1st and 2nd col). Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used an in situ hybridization method for the detection of mRNA in the methods of Band or Vogelstein for the detection of breast cancer

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran
Patent Examiner
April 29, 2003